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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,833	06/10/2002	Howard Green	H0535/7013	5763

23628 7590 01/05/2007
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EXAMINER	
NAFF, DAVID M	
ART UNIT	**PAPER NUMBER**
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,833	GREEN ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,20,22 and 74-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 20, 22 and 74-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/06 has been entered.

An amendment filed 10/6/06 amended claims 1, 9 and 20.

Claims examined on the merits are 1-13, 20, 22 and 74-77, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 8 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claims 8 and 76 are confusing by not having clear antecedent basis in the claims on which they depend for dihydroxyacetone being a reactive moiety.

Response to Arguments

The amendment asserts that the first reactive moiety in claims 1 and 9 is a general formula that includes dihydroxyacetone. This should be made clear in claims 8 and 76 by after "is" in line 1 of the

claims inserting --- the reactive moiety (recite formula) and the moiety is ---.

Claim Rejections - 35 USC § 102

Claims 1, 2, 5-7, 9-11, 20, 74, 75 and 77 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Green et al (6,267,957 B1).

The claims are drawn to a composition comprising a compound having a structure of the formula X_2—L_2—A—L_1—X_1, wherein A is an agent, L_1 and L_2 are linkers or bonds, X_1 and X_2 are reactive moieties selected from specific moieties containing an R molecule selected from organic and inorganic molecules. X_2 and L_2 can be absent leaving A—L_1—X_1 as the compound. Also claimed is a method of attaching an agent to a body tissue using the compound, and a pharmaceutical composition containing the compound and a carrier.

Green et al disclose attaching agents to proteinaceous material such as body tissue. The agent can be provided with a functional group to facilitate attachment (col 9, lines 21-25). Functional groups can be provided by reacting the agent with a bifunctional cross-linker (col 9, lines 34-40). The cross-linker can be disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate (col 9, lines 45-47).

When providing the agent of Green et al with a function group using disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate, a compound, compositions and method as required by the present claims will result, or be obvious. The agent of Green et al can be an enzyme

(col 6, line 57) or a nonprotein (col 27, line 28), can be in a pharmaceutical composition (col 13, line 29), and a microparticle does not have to be present. Green et al intend using the agent in a method of attaching the agent to tissue. Furthermore, it would have been obvious to select disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate from the cross-linkers disclosed by Green et al to provide a functional group on the agent. It would have also been obvious to use the functional group-containing agent for attaching the agent to tissue or in a pharmaceutical composition as suggested by Green et al.

Response to Arguments

The amendment urges that if disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate is reacted with an agent as disclosed by Green et al, the resultant conjugate will not be able to covalently attach to a proteinaceous material as the amended claims now require X_1 and X_2 to be capable of doing. However, after reacting disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate with an agent as disclosed by Green et al, a free succinimidyl group will remain that can covalently attach to a protein. Disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate contain two succinimidyl groups and only one reacts with the agent leaving the other free to react with a proteinaceous material. A free succinimidyl group as contained by Bis-N-hydroxy-succinimide shown by Formula II on page 6 of the present specification will remain as a reactive group for reacting with a protein. This free succinimidyl group will be the reactive moiety D

disclosed on page 3 of the present specification, which is a specific reactive moiety of the claims. The present specification discloses (page 22, lines 19 and 20) the cross-linkers, disuccinimidyl suberate as bis(sulfosuccinimidyl), as linkers that can be used. The claims do not exclude the reactive moiety X_1 being an un-reacted succinimidyl of a bi-functional cross-linker that has been reacted with the agent. A method of use and pharmaceutical composition as required by claims 9 and 20, respectively, would have been obvious uses of the composition of claim 1 since Green et al disclose a pharmaceutical composition and a method of attaching the agent to tissue.

Claim Rejections - 35 USC § 103

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al.

The claim requires a kit comprising a package housing, a container containing the composition of claim 1 and instructions for use.

Green et al disclose providing a kit (col 2, line 31).

When providing the agent of Green et al with a functional group using disuccinimidyl suberate or bis(sulfosuccinimidyl) as set forth above, it would have been obvious to put the functionalized agent in a kit for later use. Putting instructions on the kit would have been obvious to enable one to use the kit properly.

Claim Rejections - 35 USC § 103

Claims 3, 4, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al in view of Cheng et al (6,080,566).

The claims require the agent to be an enzyme that degrades nerve agents. The enzyme can be OPAA anhydrolase or OPA anhydrase.

Green et al is described above.

Cheng et al disclose degrading nerve agents with OPAA or OPA (col 1, lines 50-55).

It would have been obvious to use as the enzyme agent of Green et al an OPAA or OPA enzyme to obtain its function to degrade a nerve agent as suggested by Cheng et al.

Claim Rejections - 35 USC § 103

Claims 8 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al in view of Fusaro (3,920,808).

The claims require dihydroxyacetone as a functional moiety of the compound.

Green et al is described above.

Fusaro discloses dihydroxyacetone as being reactive with amino derivatices of protein in human skin (col 2, lines 52-65).

It would have been obvious to use dihydroxyacetone to provide a functional group on the agent of Green et al to obtain the function of the dihydroxyacetone to react with protein as disclosed by Fusaro.

Response to Arguments

The amendment urges that in view of the amended claims, and the arguments traversing the 102, alternative 103 rejection, the above rejections of claims 3, 4, 8, 12, 13, 22 and 76 are moot. However, as set forth above, reacting an agent with disuccinimidyl suberate or bis(sulfosuccinimidyl) suberate as disclosed by Green et al will leave a free succinimidyl group that can react with a proteinaceous material. Therefore, this rejection is not moot.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David M. Naff
Primary Examiner
Art Unit 1657

DMN
12/23/06